TITLE: Apparatus for Directional Guidance of a Vascular Device and Method of Use

BACKGROUND OF THE INVENTION

RELATED APPLICATIONS:

This application claims priority and is entitled to the filing date of U.S. Provisional application Ser. No. 60/462,615 filed April 14, 2003, and entitled "Apparatus for Directional Guidance of a Catheter." The contents of the aforementioned application are incorporated by reference herein.

INCORPORATION BY REFERENCE:

Applicant(s) hereby incorporate herein by reference, any and all U. S. patents, U.S. patent applications, and other documents and printed matter cited or referred to in this application.

FIELD OF THE INVENTION:

This invention relates generally to surgical methods, and more particularly to a catheter apparatus and method of use for directional guidance of vascular devices.

DESCRIPTION OF RELATED ART:

The following art defines the present state of this field:

Douglas, U.S. 4,195,624 describes a device for facilitating insertion of an endoscope into the esophagus which includes an elongated tube composed of a flexible elastomer, the tube having a substantially uniform outer diameter along most of its length and a solid tapered tip end, the tip end being joined to the remainder of the tube by means of a hollow tapered neck

portion. The tube is provided with an opening behind the neck of generally elongated configuration. The geometry of the opening and the flexibility of the tube are such that when the distal end of an endoscope is inserted into the aperture, the distal end is slightly bent and is received in wedged engagement within the tapered neck portion, and a portion immediately behind the distal end of the endoscope is resiliently supported by a portion of the periphery of the opening formed in the tube.

Arenas et al., U.S. 4,676,249 describes a multi-mode guidewire selectively allowing the creation of varying degrees of flexibility at varying locations of the guidewire. An elongate coiled wire body of the guidewire is capable of assuming an arcuate shape adjacent to its capped distal end. The coiled wire body may be made less flexible by a curve control core wire which is positionable by means of a knob at its proximal end. The curve control core wire includes a region of moderate flexibility in its distal region which can be stiffened by a stiffening member. The stiffening member is positionable by a handle located at its proximal end. A method of advancing a catheter and the guidewire includes selecting a most advantageous mode of use of the guidewire for advancement.

Hawkins et al., U.S. 4,799,495 describes a localization needle assembly including an outer tubular cannula and an inner needle slidably mounted for movement within the outer cannula between extended and retracted portions, the needle having a pointed tip which projects from the front end of the assembly when the needle is extended while the surgeon locates a lesion. When the tip is retracted, a barb, which is secured to the needle, is deployed through an opening in the sidewall of the outer cannula when the needle is retracted, the barb anchoring the needle assembly in body tissue in the proximity of the lesion. Detachable handles are provided for locking the inner needle and outer cannula together and to facilitate extension and retraction of the needle. In one embodiment, the outer cannula has a helical screw tip for securing the needle assembly to a body organ or body tissue. A guide assembly is advanced along the needle assembly, which has been inserted into the body tissue to locate a lesion to

position one end of a guide wire at the lesion to facilitate the introduction of a surgical instrument into the body and guidance of same directly to the lesion.

Jacobsen et al., U.S. 5,916,194 describes a catheter/guide wire steering mechanism including a catheter having a proximal end, a distal end, and sidewalls which define at least the first lumen. An opening is formed in a sidewall of the catheter, near the distal end thereof in communication with the first lumen. A plug is disposed in the catheter at the distal end thereof and includes a curved surface for deflecting and directing out the opening, the leading end of a guide wire (or other catheter) inserted into the lumen at the proximal end of the catheter. This enables guiding the guide wire laterally from the catheter either into a passageway branching from the main passageway into which the catheter is inserted, or to perforate a sidewall of the main passageway.

Haaga, U.S. 6,162,203 describes a cargo delivery device having coaxial, telescopically interengaged cargo delivery needle, an outer cannulas which are axially and rotatably displaceable relative to one another. The cargo delivery needle has a distal portion provided with a cargo recess for carrying a cargo to a site in a patient.

Burney et al., U.S. 6,203,524 describes a guide for biopsy and microtherapy which includes an introducer cannula defining a lumen sized to receive a diagnostic or therapeutic item therethrough and a lateral opening in communication with the lumen adjacent the first end of the cannula. The invention also includes a solid tip having an anatomically distal end secured to the first end of the cannula and a proximal end configured to pierce tissue. A ramp is disposed within the cannula at an end of the lateral opening adjacent the first end of the cannula. The ramp is inclined toward the lateral opening, whereby the item will be deflected through the lateral opening as it advances within the lumen and exits the cannula. In some embodiments, the item is a biopsy needle, ablation means or a radiopharmaceutical seed. The invention also includes methods of obtaining a biopsy sample and methods for treating lesions.

Burney et al., U.S. 6,447,477 describes a guide for biopsy and microtherapy which includes an introducer cannula defining a lumen sized to receive a diagnostic or therapeutic item therethrough and a lateral opening in communication with the lumen adjacent the first end of the cannula. The invention also includes a solid tip having an anatomically distal end secured to the first end of the cannula and a proximal end configured to pierce tissue. A ramp is disposed within the cannula at an end of the lateral opening adjacent the first end of the cannula. The ramp is inclined toward the lateral opening, whereby the item will be deflected through the lateral opening as it advances within the lumen and exits the cannula. In some embodiments, the item is a biopsy needle, ablation means or a radiopharmaceutical seed. The invention also includes methods of obtaining a biopsy sample and methods for treating lesions.

Carrillo, Jr. et al., U.S. 6,52,951 describes a single operator exchange biliary catheter having a common distal lumen. The biliary catheter includes an elongate shaft having a proximal portion defining an ancillary lumen and a distal portion defining a common guidewire and ancillary lumen. The common distal lumen reduces the profile of the distal portion of the shaft. The elongate shaft also includes a proximal guidewire port disposed between the proximal end of the shaft and the distal end of the shaft to facilitate single operator use. A seal may be disposed adjacent the proximal guidewire port to thereby seal the port. Preferably, the shaft includes a single lumen distal portion and a bitumen proximal portion. The single lumen distal portion of the shaft may be curved and may include a tapered or spherically shaped distal tip.

Mehier, U.S. 2001/0034502 describes a device for directly delivering an active substance within all or part of a human or animal tissue cell, characterized in that it is in the form of a hollow tube (1), whereof the walls in contact with said tissue are provided with perforations (5) and whereof the distal end (2) is sealed, while the proximal end (3) is shaped so as to

receive removable closing means, said tube being capable of bearing a pressure of at least 50 bars.

Our prior art search with abstracts described above teaches a tubular sheath for facilitating the insertion of an endoscope, a multi-mode guidewire, a localization needle assembly, a catheter/guide wire steering apparatus and method, a cargo delivery needle, a surgical and pharmaceutical site access guide and methods, a rapid exchange catheter with detachable hood, and a device for directly delivering an active substance within a cell tissue and means for implanting said device and appliances for injecting active substance into said device, but does not teach a catheter apparatus configured with an open-ended channel so as to guide or direct a non-coaxially introduced vascular device such as a catheter, guidewire, balloon catheter or pacing electrode catheter. Specifically, in the context of the difficult task of placing such a vascular device in the coronary sinus when the device has entered the heart's right atrium through the superior vena cava, the prior art does not teach an apparatus and method that when placed in the right atrium through the inferior vena cava, has the capability to guide a vascular device into the coronary sinus. The present invention fulfills these needs and provides further related advantages as described in the following summary.

SUMMARY OF THE INVENTION

The present invention teaches certain benefits in construction and use which give rise to the objectives described below.

The present invention is an apparatus and method of use for directional guidance of a vascular device and includes a flexible insertion device terminating in a distal end with a channel formed in the insertion device so as to intersect the distal end. The insertion device comprises an inner guiding catheter and an outer deflecting catheter configured with a tubular wall defining an interior lumen such that the deflecting catheter is positioned coaxially and slidably about the guiding catheter along at least a portion of the lumen, the

tubular wall having the channel formed therein so as to communicate with the lumen and intersect the deflecting catheter's distal tip. The deflecting catheter may be further configured with a pre-formed bend.

In use, the apparatus is advanced along a first body lumen and into a body cavity where it is then manipulated so as to seat the guiding catheter's distal tip within a second body lumen. The pre-formed bend of the deflecting catheter facilitates orienting the guiding catheter's distal tip adjacent to the second body lumen. The apparatus is then advanced within the second body lumen such that the channel formed in the deflecting catheter is partially positioned within the second body lumen and partially positioned within the body cavity. With the apparatus so positioned, the guiding catheter is retracted and the vascular device is advanced along a third body lumen and into the body cavity. The vascular device's distal tip is then positioned within the exposed channel, enabling the vascular device to be advanced into the second body lumen as guided by the channel. Retracting the apparatus within the first body lumen leaves the distal tip of the vascular device positioned within the second body lumen.

A primary objective of the present invention is to provide an apparatus and method of use of such apparatus that provides advantages not taught by the prior art.

Another objective is to provide such an invention capable of directionally guiding a non-coaxially introduced vascular device.

A further objective is to provide such an invention capable of being retracted after directionally guiding a non-coaxially introduced vascular device.

A still further objective is to provide such an invention capable of being advanced through a first body lumen and into a body cavity to be partially seated within a second body lumen so

that a vascular device entering the body cavity through a third body lumen may be guided into the second body lumen.

Other features and advantages of the present invention will become apparent from the following more detailed description, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings illustrate the present invention. In such drawings:

Figure 1 is a perspective view of the preferred embodiment of the invention shown in its pre-formed, bent configuration with a fluid dispensing device adjacent its proximal end;

Figure 2 is a partial top view of a deflecting catheter thereof; and

Figures 3-8 are schematic diagrams showing the sequence of the preferred method of use thereof for guiding a vascular device within the heart's right atrium.

DETAILED DESCRIPTION OF THE INVENTION

The above described drawing figures illustrate the invention in at least one of its preferred embodiments, which is further defined in detail in the following description.

The present invention is an apparatus **10** for directional guidance of a vascular device **70** (Figs. 3-8) generally comprising a flexible insertion device **20** terminating at a distal end **22** and a channel **60** (Fig. 2) formed in the insertion device **20** so as to intersect the distal end **22**, the channel **60** being configured to slidably receive the vascular device **70** and guide the vascular device **70** toward the distal end **22**. In a preferred embodiment, the insertion device

20 comprises an inner guiding catheter **30** and an outer deflecting catheter **40**. The deflecting catheter **40** terminates at a distal deflecting tip **42** and is configured with a tubular wall **44** defining an interior lumen **46** (Fig. 2) such that the deflecting catheter **40** is positioned coaxially and slidably about the guiding catheter **30** along at least a portion of the lumen **46**. The guiding catheter **30** is formed with a tapered distal guiding tip **32**. As best shown in Fig. 2, the channel **60** is formed in the tubular wall **44** of the deflecting catheter **40** so as to communicate with the lumen **46** and intersect the deflecting tip **42**. While the channel **60** is shown as having a substantially rectangular profile, it will be appreciated that other profiles, such as elliptical and semi-elliptical, may be employed as well. The channel **60** is formed having a sufficient length, width and depth so as to transversely receive and axially guide the vascular device **70**, as explained more fully below. In the preferred embodiment, the channel is approximately 1.5" long, approximately 0.1" wide, and approximately 0.07" deep, though it will be appreciated by those skilled in the art that the channel can take on different dimensions to optimally suit different applications. The deflecting catheter **40** has a relatively long, substantially linear proximal portion **48** and a relatively short, substantially linear distal portion **50**. A pre-formed bend **52** of up to about **85** angular degrees is formed between the proximal and distal portions such that the distal portion **50** is angled relative to the proximal portion **48** so as to have a superior aspect **54** in which the channel **60** is formed. The guiding catheter **30** may be formed with a complimentary bend. Both catheters are formed through a conventional extrusion technique from a flexible, resilient, medical-grade plastic so as to have structural memory, as is known and used in the art, that is, the plastic material, once formed into a desired shape, retains memory of that shape and is thereafter biased to resume that shape after being deformed into an alternate shape. Such structural memory is achieved in the present invention by the cooperation of the plastic material and the pre-formed bend **52** and this enables the catheter apparatus **10** to function as described below. The deflecting tip **42** of the deflecting catheter **40** is formed with a corner-break **56** so as to produce a smooth transition with the guiding catheter **30** when the guiding catheter **30** is coaxially inserted within the interior lumen **46** of the deflecting catheter **40** such that the guiding catheter's guiding tip **32** protrudes beyond

the deflecting catheter's deflecting tip **42**. The opposite proximal end **58** of the deflecting catheter **40** is formed with a hemostatic valve as is known in the art so as to prevent fluids from passing along the lumen **46** and out the deflecting catheter's proximal end **58**. The deflecting catheter **40** is preferably a size 10 or 11 French, though it will be appreciated by those skilled in the art that other catheter sizes may be employed without departing from the spirit and scope of the invention. The guiding catheter **30** is formed with an axial through-hole **34** communicating between the guiding catheter's proximal and distal ends for the passage of a guidewire (not shown) or the delivery of fluids therethrough. The proximal end **36** of the guiding catheter **30** is configured with a universal hub connection **38** to facilitate attaching a fluid delivery device **80**, such as a syringe, fluid line connector or other device, to the guiding catheter **30**. While the preferred embodiment of the present invention is shown and described as a pair of coaxially positioned catheters, it will be appreciated by those skilled in the art that the flexible insertion device **20** of the directional guidance apparatus **10** may be comprised of various other combinations of catheters, including a single catheter, without departing from the spirit and scope of the invention.

In a preferred use, the apparatus **10** of the present invention is employed to provide mechanical guidance of a vascular device **70**, such as a catheter, guidewire, balloon catheter, or pacing electrode catheter, introduced through the superior vena cava **110** into the right atrium **100** and directed toward the os **122** of the coronary sinus **120**. Such a procedure is often employed in the specific context of biventricular cardiac pacing, wherein one or two pacing electrodes (not shown) are placed in a heart's right ventricular chamber, or right atrium **100**, and a third pacing electrode, or vascular device **70** is placed in a branch of the coronary sinus **120** (Fig. 8) to effect pacing of the left ventricle (not shown). As is known in the art, placement of pacing electrodes **70** in the coronary sinus **120** has been challenging due to the lack of visible landmarks, the variable shape, size and location of the os **122** of the coronary sinus **120**, the variable anatomy of the branches (not shown) of the coronary sinus **120** beyond the os **122**, and the pumping motion of the heart (not shown). While the catheter apparatus **10** of the present invention is particularly well-suited for guiding and

directing such a pacing electrode **70** into the coronary sinus **120**, as explained in more detail below, it will be appreciated that the apparatus **10** and its method of use are also capable of functioning to guide and direct catheters and the like in any medical procedure in which it is advantageous to provide the mechanical guidance from a direction or body lumen other than that of the catheter itself.

For the preferred embodiment and method of use, the catheter apparatus **10** of the present invention is configured as described above with the deflecting catheter **40** coaxially and slidably positioned about the guiding catheter **30** such that the guiding catheter's guiding tip **32** protrudes beyond the deflecting catheter's deflecting tip **42** so as to cooperate in forming a tapered distal end **22**. As such, the apparatus **10** is configured substantially as shown in Fig. 1 and is ready for insertion within a body lumen. In the present exemplary application, the catheter apparatus **10** is advanced through either the right or left femoral vein (not shown) and into a first body lumen **130**, the inferior vena cava. Because the guiding catheter **30** and deflecting catheter **40** are formed from a flexible plastic, it will be appreciated that the catheter apparatus **10** is able to flex from its pre-formed, bent configuration so as to conform to the anatomical structures through which the apparatus **10** is being advanced; in this case, the inferior vena cava **130**. Thus, as best shown in Fig. 3, the catheter apparatus **10** is substantially linear as it passes through the inferior vena cava **130** and begins to enter the body cavity or right atrium **100**. Upon further advancement of the catheter apparatus **10**, as shown in Fig. 4, the distal portion **50** and the bend **52** of the outer deflecting catheter **40** is located within the right atrium **100** and the deflecting catheter **40** is then free to return to its original shape. The apparatus is then manipulated so as to orient the angled distal portion **50**, and the distal tip **32** of the guiding catheter **30**, specifically, toward the os **122** of the second body lumen, the coronary sinus **120**. As shown, because the channel **60** is located on the superior aspect **54** of the deflecting catheter's distal portion **50**, the channel **60** is oriented toward the third body lumen, the superior vena cava **110**, through which the vascular device **70** is introduced. This orientation is critical to the guiding function of the catheter apparatus **10**, as explained more fully below. With the catheter apparatus **10** so positioned within the

right atrium **100**, the apparatus **10** is then manipulated as shown in Fig. 5 so as to seat the tapered distal tip **32** within the os **122** of the coronary sinus **120**. It will be appreciated by those skilled in the art that the tapered distal tip **32** serves to locate within the os **122** of the coronary sinus **120** while reducing the risk of damaging any of the vascular anatomy. Once this positioning of the catheter apparatus **10** is verified, as by fluoroscopic confirmation, the apparatus **10** is advanced further within the coronary sinus **120** such that the channel **60** is partially positioned within the coronary sinus **120** and partially positioned within the right atrium **100**. As with the tapered distal tip **32** of the guiding catheter **30**, the corner-break **56** (Fig. 1) formed on the distal tip **42** of the deflecting catheter **40** also reduces the risk of trauma to the os **122** and the coronary sinus **120** as the catheter apparatus **10** is advanced to the seated position shown in Fig. 6. With the catheter apparatus **10** so seated within the coronary sinus **120**, the vascular device **70** is advanced within the superior vena cava **110** and into the right atrium as shown in Figs. 3-6. As shown in Fig. 7, the guiding catheter **30** is then retracted within the deflecting catheter **40** so as to expose the interior lumen **46** (Fig. 2) to the right atrium **100** through the channel **60**. Next, the vascular device **70** is advanced further into the right atrium **100** so as to locate its distal tip **72** within the channel **60**. Because the channel **60** is formed in the superior aspect **54** of the deflecting catheter **40** such that the channel **60** is oriented generally toward the superior vena cava **110** when the deflecting catheter **40** is seated within the coronary sinus **120**, it will be appreciated that the distal tip **72** of the vascular device **70** is then more readily located within the channel **60**. Once the distal tip **72** is so located, the vascular device **70** is simply advanced into the coronary sinus **120** as guided by the channel **60**. The deflecting catheter **40** may then be retracted about the guiding catheter **30** within the inferior vena cava **130** to leave the distal tip **72** of the vascular device **70** positioned within the coronary sinus **120**. It will be appreciated by those skilled in the art that the formation of the channel **60** within the deflecting catheter **40** so as to intersect the distal tip **42**, and thereby form a distally-open-ended channel, facilitates the retraction of the deflecting catheter **40** while leaving the vascular device **70** in position, when, as here, the vascular device **70** is introduced along a direction or body lumen other than that of the catheter apparatus **10**.

While the invention has been described with reference to at least one preferred embodiment, it is to be clearly understood by those skilled in the art that the invention is not limited thereto. Rather, the scope of the invention is to be interpreted only in conjunction with the appended claims and it is made clear, here, that the inventor(s) believe that the claimed subject matter is the invention.

NEW APPLICATION DOCUMENT INDEX SHEET

A DOCPHOENIX

- ☐ TRNA _____ Transmittal New Application
- ☐ SPEC _____ Specification
- ☑ CLM 6 Claims
- ☐ ABST _____ Abstract
- ☐ DRW _____ Drawings
- ☐ OATH _____ Oath or Declaration

- ☐ ADS _____ Application Data Sheet
- ☐ A... _____ Amendment Including Elections
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- ☐ REM _____ Applicant Remarks in Amendment

- ☐ IDS _____ IDS Including 1449
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- ☐ LET. _____ Misc. Incoming Letter
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- ☐ APPENDIX _____ Appendix
- ☐ COMPUTER _____ Computer Program Listing
- ☐ SPEC NO _____ Specification Not in English
- ☐ N417 _____ Copy of EFS Receipt Acknowledgement

- ☐ CRFL _____ Computer Readable Form Transfer Request Filed
- ☐ CRFS _____ Computer Readable Form Statement
- ☐ SEQLIST _____ Sequence Listing
- ☐ SIR. _____ SIR Request

- ☐ AF/D _____ Affidavit or Exhibit Received
- ☐ DIST _____ Terminal Disclaimer Filed
- ☐ PET. _____ Petition

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